MAR 2 6 2002

510(k) Summary for Mission Diagnostic Reagents on Corning 6X4 Electrolyte Analyzers

K020596

1. **Submitter's Name & Address**

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:

Linda Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: In Process

Date of Preparation: February, 19, 2002

2. **Identification of the Device:**

Proprietary/Trade name:	Calibrating Material, Cal-Pak, Cal & Slope Standards
Common or usual name	Calibrators for ISE and/or pH/Blood Gas automated systems
Classification name:	Calibrator, secondary
Device Classification	II
Regulation Number:	21 CFR § 862.1150
Panel:	Chemistry (75)
Product Code:	JIT

1.

2. **Predicate Device:**

Mission claims substantial equivalence to the Corning Calibrators listed below:

Mission Product		Corning Equivalent	
CD-478541AD	Cal-Pak for Corning 614	478541	614 Cal-Pak Na+/K+
CD-478548AD	Cal Pak for Corning 634	478548	634 Cal-Pak Ca++/pH
CD-473510AD	Cal-Pak for Corning 644	473510	644 Cal-Pak Na+/K+/Cl-
CD-473605AD	Cal-Pak for Corning 654	473605	654 Cal-Pak Na+/K+/Li+

3. **Device Description:**

The Calibrators for the Corning Electrolyte Instruments are aqueous reagents with salts added to obtain desired analyte levels to provide calibration of the electrodes and rinse the sample path.

4. **Intended Use:**

- The reagents are intended for use on equivalent Corning Electrolyte Instruments to calibrate the electrodes and flush the sample flow path.
- Corning is the original equipment manufacturer (OEM) of the instruments and the predicate reagents which are necessary for the continued operation and use of the instruments.
- The Mission reagents are intended to serve as direct replacements to like named products manufactured by Corning.
    - The OEM products were originally released under the Corning name.

- Corning has under gone several owner and name changes:
  Corning Glass, Ciba-Corning, Chiron, and currently Bayer.
- For the purposes of this 510(k) the OEM will be referred to as Corning.

- Mission uses a similar composition, description and packaging as that used by Corning in its products, as shown in the packaging section of this submission.

- Performance equivalence was shown in the following manner:
  - Precision data was collected from QC samples (or control material) measured over a minimum of 7 days on an equivalent Corning analyzer where Mission products were installed.
  - Correlation of serum sample results obtained on an equivalent Corning analyzer, calibrated with Mission reagents and on the same analyzer calibrated with Corning reagents

A summary of the results of these studies follows:

Performance Characteristics:

Precision Data

Precision data were collected from the analysis of three levels of control materials, measured three times within a run, testing over a minimum of 7 days on each Corning analyzer calibrated with all Mission reagents.

Precison Data Table 1 Corning 614 Electrolyte Instrument

Three levels of QC Material, Na, K precision values with Mission reagents.

Corning	614

Na

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	24	112	0.9	110	113	0.79%
QC2	24	136	0.7	134	137	0.50%
QC3	24	159	0.8	158	161	0.50%

Corning	614

K

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	24	1.93	0.032	1.85	1.99	1.67%
QC2	24	4.17	0.019	4.13	4.20	0.46%
QC3	24	6.58	0.060	6.49	6.72	0.92%

Precison Data Table 2 Corning 644 Electrolyte Instrument

Three levels of QC Material, Na, K, Cl precision values with Mission reagents.

Corning	644

Na

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	24	108	0.6	107	109	0.56%
QC2	24	133	1.1	132	138	0.85%
QC3	23	157	1.1	155	159	0.72%

Corning	644

K

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	24	1.93	0.022	1.89	1.98	1.13%
QC2	24	4.10	0.016	4.08	4.14	0.40%
QC3	23	6.51	0.044	6.45	6.60	0.68%

Corning	644

Cl

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	24	81	1.1	79	84	1.40%
QC2	24	97	1.9	95	103	1.99%
QC3	23	128	2.4	125	135	1.85%

Precison Data Table 3 Corning 654 Electrolyte Instrument

Three levels of QC Material, Na, K, Li precision values with Mission reagents.

Corning	654

Na

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	21	109	1.9	104	113	1.75%
QC2	24	135	1.4	133	140	1.06%
QC3	24	159	2.1	154	163	1.32%

Corning	654

K

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	21	1.87	0.028	1.82	1.92	1.49%
QC2	24	4.10	0.027	4.04	4.16	0.65%
QC3	24	6.54	0.074	6.36	6.65	1.14%

Corning	654

Li

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	21	0.29	0.026	0.24	0.35	8.89%
QC2	24	0.99	0.032	0.90	1.03	3.27%
QC3	24	2.24	0.084	2.05	2.36	3.75%

Correlation with Corning Reagents

Correlation data were obtained from human serum samples for Na, K, Cl, Ca, and Li.

- Serum was first spiked with LiCl to obtain a base Li concentration.
  - Samples were then spiked to yield varying concentrations of each of the measuring analytes.
- Not all runs were specific for all analytes.
- Serum samples were measured each test day on Corning analyzers calibrated with Mission reagents for 1 run then measured in a comparative run on Corning analyzers calibrated with Corning reagents.

Linear regression analysis was performed using Mission data as the independent X variable and Corning as the dependent Y variable in the equation Y = mX +b

Correlation Data Table 1

Na

	N	Slope	Interecept	R^2	Range
614	50	1.00	1.72	1.00	105 - 187
644	50	1.03	0.25	1.00	100 - 190
654	50	0.97	4.41	1.00	102 - 189

K

	N	Slope	Interecept	R^2	Range
614	60	1.01	-0.01	1.00	2.53 - 6.31
644	60	1.04	-0.11	1.00	2.47 - 6.24
654	60	1.07	-0.20	1.00	2.43 - 6.45

		N	Slope	Interecept	R^2	Range
644	Cl	50	0.97	6.20	1.00	81 - 187
654	Li	30	0.96	0.06	0.99	0.32 - 1.54

- Correlations demonstrated slopes of 1.0 and R^2 's of ≥ 0.99, which support a claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 6 2002

Diamond Diagnostics Inc.
c/o Ms. Linda Stundtner
QA/RA Manager
Mission Diagnostics
333 Fiske Street
Holliston, MA 01746

Re: k020596
Trade/Device Name: Mission Diagnostic Calibrating Reagents for Corning 6X4 Electrolyte Analyzers
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: February 19, 2002
Received: February 22 2002

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k(Number K020596

Device Name: Mission Diagnostic Calibrating Reagetns for Corning 6X4 Electrolyte Analyzers

Indication For Use:

The products encompassed by this request are intended for in-vitro diagnostics use and for use in calibrating the electrodes and flushing the sample flow path of the equivalent Corning 6X4 Series Electrolyte Analyzers. Corning (name changes incl.: Corning Glass, Ciba-Corning, Chiron, and currently Bayer) is the Original Equipment Manufacturer (OEM) of the analyzers and the predicate reagents.

Mission Product	Corning Instrument Used on
CD-478541AD Cal-Pak for Corning 614	614
CD-478548AD Cal Pak for Corning 634	634
CD-473510AD Cal-Pak for Corning 644	644
CD-473605AD Cal-Pak for Corning 654	654

Mission reagents are intended to serve as direct replacements to like named products manufactured by Corning (under the label of current owner, Bayer).

The products encompassed are to be handled using normal laboratory precautions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of the Device Evaluation (ODE)

prescription use ✓

Carol C Benson for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020596

(Optional format 3-10-98)